

## REMARKS

Claims 1-8, 10-15, 17-23 and 26-28 are pending in the application. Claims 9, 16, 24, 25 and 29-42 have been canceled. Claims 1, 20 and 23 have been amended herein. The amendments to claims 1 and 20 are supported by disclosure at page 4, lines 20-21 of the specification. The amendment to claim 23 is supported by disclosure at page 5, lines 2-3 of the specification. No matter has been added.

### Claim Rejections

#### 35 U.S.C. 102(e)

Claims 1-8 and 16-27 have been rejected under 35 U.S.C. 102(e) as being anticipated by Vernice (U.S. Pat. 6,117,419; "the '419 patent"). Applicants traverse.

The '419 patent discloses flakes and a method for making flakes for use in topical applications. Claim 1 of the '419 patent recites "[a] method of forming flakes for use in a topical skin preparation . . . ." Moreover, the specification, including all of the illustrative examples, is directed to topical preparations.

In contrast, claims 1 and 20 of the instant application have been amended to recite that the flakes as claimed are suitable for oral ingestion. The current specification explains that spherical or granular particulates leave a gritty sensation in the mouth. The present invention is directed to an oral drug delivery vehicle, in the form of a flake with enhanced mouth feel due to the elimination or reduction of gritty particles. (*See* Specification at page 6, lines 26-32).

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). As stated above, the flakes of the present invention are designed to be orally ingestible. The '419 patent does not teach flakes suitable for oral ingestion. Therefore, the '419 patent does not anticipate the invention as claimed. Thus, Applicants request reconsideration and withdrawal of this rejection.

As to the claimed porous flakes, it is the controlled dimensional specifications and outer surface composition that results in the porous characteristics, not an inorganic particulate such as Cloisonne Gold pigment. While porous metal oxides such as Cloisonne Gold may be useful in topical cosmetics, they are antithetical to use in the flakes of the current invention. First, metal oxides can and do act as catalysts, which could either degrade a pharmaceutical or potentially create a new compound that was not intended. Second, certain metal oxides are toxic, such as the oxides of copper, mercury, cadmium and thallium. Third, certain oxides, including iron oxides, in combination with certain drugs can enhance the toxicity of one another. None of these characteristics would generally be acceptable in any human drug delivery system whether oral or topical. Therefore, metal oxide are not part of the current invention. Thus, the '419 patent does not teach to the subject matter of the current application, and Applicants request reconsideration and withdrawal of this rejection.

35 U.S.C. 112, second paragraph

Claim 23 has been rejected as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. According to the Examiner, the term "condition" is vague. Claim 23 has been amended to further clarify that said condition is a condition which makes it difficult to swallow. Therefore claim 23 as amended is clear and definite, and Applicants request reconsideration and withdrawal of this rejection.

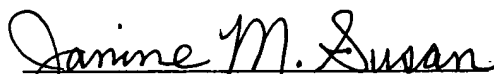
Claim Objections

Claims 10-15 and 28 have been objected to as dependent upon a rejected claim. In light of the amendments to claims 1 and 20 and the remarks presented above, Applicants request reconsideration and withdrawal of this objection.

## SUMMARY

Applicant submits that the claims, as amended herein, are in condition for allowance. The Examiner is encouraged to call the undersigned attorney at (617) 854-4069 should he determine that a telephonic interview would expedite prosecution of this case.

Respectfully submitted,

A handwritten signature in cursive script that reads "Janine M. Susan".

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